

### **REMARKS**

Applicants have carefully reviewed the Examiner's remarks presented in the Advisory Action mailed January 28, 2005, in which Applicants' proposed amendments were not entered. A Final Office Action was mailed November 17, 2004, in the application. This Amendment and the accompanying RCE are submitted within the three-month shortened statutory period for reply provided in the Final Office Action, therefore, no extension of time is necessary.

Currently claims 1-35 are pending in the application, wherein claims 1-35 have been rejected by the Examiner. Claim 20 has been amended with this paper to recite that the polymer jacket comprises a shape memory polymer. Applicants assert this limitation already existed in claims depending from claim 20, and claim 20 is amended to provide proper antecedent basis in compliance with the requirements of 35 U.S.C. §112, Second Paragraph. Favorable consideration of this amendment and the accompanying remarks is respectfully requested.

Claims 1-4 and 20-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dubrul (U.S. Patent No. 5,944,701). Applicants respectfully traverse this rejection. Drawing the Examiner's attention to remarks submitted on January 14, 2005, in response to the Final Office Action, Applicants respectfully assert that these claims are indeed allowable over Dubrul.

As asserted in the previous paper, Dubrul fails to teach a guidewire including a metallic core wire and a shape memory polymer jacket attached to and surrounding a portion of the core wire as currently claimed. In suggesting that Dubrul in fact does teach a polymer jacket comprising a shape memory polymer, the Examiner asserts, "The polymer jacket as disclosed by Dubrul has a coiled configuration (Col. 3, lines 35-39). The polymer jacket then assumes a straitened [sic] configuration (Col. 3, lines 39-44). The polymer jacket then again assumes a coiled configuration (Col. 3, lines 11-22)." Applicants are perplexed by the Examiner's assertion that "[b]ecause the polymer has one configuration, transforms to another and then again assumes the first configuration, it is considered to be a shape memory polymer." Applicants assert the Examiner's reasoning in this assertion is in error. It is not logical to conclude that a polymer coating having one configuration, which transforms to another and then again assumes the first configuration, is necessarily a shape memory polymer. For instance, a common electrical wire having a polymer coating may be purchased in a coiled configuration, subsequently straightened

during use, and then bent into a curved configuration. These characteristics don't suggest that every electrical wire includes a shape memory polymer coating.

Relevant to this inquiry, Dubrul teaches at column 3, lines 27-44:

Guidewires formed from shape memory alloys may be shaped to have a straightened configuration at room temperature, with a coil configuration maintained by covering the body with a polymeric coating which constrains the guidewire or catheter in the coil. After introduction to the body lumen, i.e. raising the temperature to body temperature, the shape memory alloy would convert to the superelastic configuration (while still being in a straightened geometry), thus overcoming the coil force of the polymer coating.

Applicants assert Dubrul discloses that it is the characteristics of the shape memory alloy that allow the guidewire to convert from a coiled configuration, to a straight configuration, and back to a coiled configuration as a result of changes in temperature. The sole reason the polymer coating is able to assume a straight configuration is due to the transformation characteristics of the shape memory alloy as it undergoes a phase transformation due to a change in temperature. The shape memory alloy guidewire must overcome the coil force of the polymer coating. Once the shape memory alloy overcomes the coil force of the polymer coating, the polymer coating must yield to the configuration of the shape memory alloy guidewire.

Dubrul suggests that a guidewire formed from a shape memory alloy may have a straightened configuration at room temperature. See column 3, lines 35-37. The guidewire may be covered with a polymeric coating which may constrain the guidewire into a coiled configuration. See column 3, lines 37-39. The shape memory alloy may overcome the coil force of the polymeric coating to return to a straightened configuration once the shape memory alloy is subjected to a body temperature. See column 3, lines 40-43. In other words, the elevated temperature causes the shape memory alloy to go through a phase change, a phenomenon associated with shape memory alloys and well known by those of skill in the art. Only when the shape memory alloy is converted to its superelastic configuration does the guidewire overcome the coil force of the polymer coating. See column 3, lines 39-44. It is the shape memory alloy, overcoming the continuous coil force provided by the polymer coating, that allows the guidewire to assume a straight configuration. When the shape memory alloy is in its superelastic phase, the polymer coating must yield to the configuration memorized by the shape memory alloy (in this instance a straight configuration). Dubrul teaches nothing more than providing a polymer

coating to a guidewire to subject it to a coiled configuration when the shape memory alloy is below its transition temperature.

Applicants assert the above discussion of the teachings of Dubrul sufficiently refutes the Examiner's remarks in the Advisory Action. Dubrul fails to disclose a metallic guidewire having a shape memory polymer jacket; therefore, claims 1-4 and 20-23 are clearly patentable over Dubrul. Withdrawal of the rejection is respectfully requested.

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Gunatillake et al. (WO 01/07499). Applicants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established. Claim 17 recites a method of shaping a guidewire, wherein the guidewire comprises an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire. As discussed above, Dubrul fails to teach a guidewire with the structural limitations of the guidewire of claim 17. Applicants respectfully assert Gunatillake fails to remedy the shortcomings of Dubrul. Therefore, at least because not every element of the claimed invention is either taught or suggested by the prior art references, Applicants assert a *prima facie* case has not been established. See M.P.E.P. §2143.03. Therefore, claim 17 is believed to be in condition for allowance and withdrawal of the rejection is requested.

Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Lafontaine (U.S. Patent No. 5,662,621). Applicants respectfully traverse this rejection, asserting no *prima facie* case has been established. For the reasons stated above, as well as those provided in Applicants' reply to the Final Office Action, regarding the deficiencies of Dubrul and the fact that Lafontaine fails to remedy the shortcomings of Dubrul, Applicants assert each and every element of the claimed invention is not disclosed by the combination of references required to establish a *prima facie* case of obviousness. Applicants assert claim 17, and therefore claims 18 and 19, are currently in condition for allowance and withdrawal of the rejection is requested.

Claims 5-16 and 24-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Takahashi (U.S. Patent No. 6,485,458). Claims 5-16 depend from claim 1 and claims 24-35 depend from claim 20. Therefore, for the reasons

stated above concerning the allowability of claims 1 and 20, Applicants respectfully assert this rejection is moot.

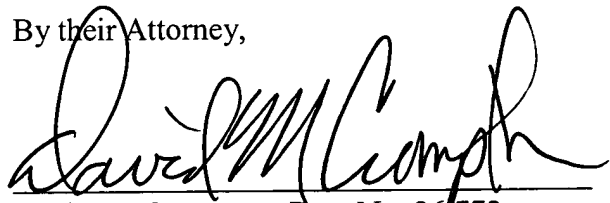
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

Date: 2/16/05

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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